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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,160	07/09/2001	Jack V. Smith		7063

7590 06/26/2003
JACK V. SMITH
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EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,160	SMITH, JACK V.	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 July 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Drawings

1. This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "13" and "14" have both been used to designate the shaft, according to specification page 10, second paragraph. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The specification is replete with spelling and/or grammatical errors. Applicant should carefully proofread the specification and correct such errors in response to this Office Action.

Claim Observations

Claim 3 fails to further limit claim 1. Each dependent claim should recite a further limitation of the claim(s) from which it depends. Claim 3 recites the assaying means being integrated into the outside wall of the assay device. This limitation already appears in lines 7-8 of claim 1. It is suggested that 3 be cancelled.

The preamble of claim 4 recites "A device", however, method steps are recited. It is suggested that Applicant amend claim 4 to recite "A method".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,277,646 to Guirguis et al.

Guirguis et al teach a device for both collecting and testing a fluid specimen, in particular urine. With respect to claim 1, the device comprises a specimen container (15) having a collection chamber (40) for collecting a fluid specimen and an opening (25) allowing fluid to be placed into the container. The device also includes a cap (20) for sealing the container. A test chamber (80) having a test agent (95) is equivalent to Applicants' claimed assay means (col. 5, line 60 – col. 6, line 3). The test agent (95) is preferably a test strip such as an immunochromatographic test strip (col. 6, lines 3-6). At col. 6, lines 63-67, Guirguis et al teach that the device may include test strips for detecting drugs of abuse or for performing multiple tests for multiple analytes. At col. 7, lines 1-6, Guirguis et al teach that at least two test strips, preferably five or six test strips may be present in the device to test for different analytes. Figures 1-3 show the test chamber being position on an outside wall of the device, as recited in claim 3. Further with respect to claim 1, Guirguis et al teach activating the assay means by penetrating a frangible bottom wall (75) of the isolation chamber (65) with a fluid releasing element (100) which is preferably in the form of a spike (102), which is equivalent to Applicant's claimed shaft means (col. 7, lines 14-24). With respect to claim 2, Guirguis et al

teach that fluid communication between the isolation chamber and the test chamber holding the test strips is facilitated by a fluid flow path (32). This fluid flow path is equivalent to Applicant's claimed lateral flow means. With respect to the method of claim 4, Guirguis et al teach, collecting a sample into the collection chamber (40) of the device, sealing the device with the lid (20), which activates the fluid releasing element (100) causing fluid to flow via the fluid flow path (32) into the test chamber (80), where the fluid contacts reagents on the test strips to analyze the constituents of the fluid. See col. 8, lines 12-42.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(e) in view of the teachings of Guirguis et al.

Citation of Relevant Prior Art

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- US Patent 5,658,531 to Cope et al teaches a device for assaying a fluid sample, which comprises a chamber having reagents for assaying (12), a sample collecting chamber (22) and piercing tube (28). The piercing tube punctures a pierceable membrane (16) enabling a predetermined amount of sample from chamber (22) to be disposed into the reaction chamber (12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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June 24, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700